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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Date August 19, 2007

Docket No. 716875.1

CERTIFICATION UNDER 37 CFR 1.8

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Transmitted herewith for filing is an amendment and related papers for:

Application of:	Korakianitis and Grandia	Art Unit:	3762
Serial No.:	10/613,949	Atty. Docket No.:	716875.1
Filed:	07/03/2003		
For:	Optimized pulsatile-flow ventricular-assist device and total artificial heart	Examiner:	Alyssa M. Alter

RESPONSE and AMENDMENT

In response to the Official Action, which was mailed on May 21, 2007, Applicant submits the following comments and amendment. A complete listing of the current claims as currently present are enclosed herewith.

Claims 32-61 stand rejected under 35 USC 112, second paragraph, as allegedly failing to provide structure and merely stating intended use. Applicant respectfully disagrees. Each of the rejected claims is clearly drawn to a device or a system, which comprise explicitly stated physical elements, one of which is a hydraulic pump. Applicant invites Examiner to provide an example of what she means as "further structure." As far as the explicit use of the term "pump," Applicant is entitled to be his own lexicographer. For the record, the "device to assist" of claims 32-38, the "system for assisting" of claims 39-55, 58, 59, and 62, the "BIVAD assembly" of claims 56 and 57, and the

“system for completely replacing” of claim 61 are construed as the pump. Applicant asks Examiner to remove the rejection under 35 USC 112, second paragraph.

Claims 32-61 stand rejected under 35 USC 101, as allegedly being directed to non-statutory subject matter. The claims 32, 35, 42, 44, 51, 52, 53, 55, 56, 57, 58, 60 and 61 have been amended to remove human components and to enable the device to be adapted for use in a patient or deployable in a patient, not being incorporated within a patient. Claim 39 does not claim human subject matter as originally drafted, but merely is directed to a device “adapted to cause movement ...” Applicant asks that this rejection be withdrawn and the claims allowed.

Claim 61 stands rejected under 35 USC 102(b) as being anticipated by patent ‘504. Examiner takes the position that the Archimedes screw of ‘504 to be equivalent to the one way valve of the instant invention. Applicant respectfully disagrees with this presumption. The artificial heart valve in the instant device is a true unidirectional device which will let fluid (blood) pass through it in only one direction in response to a pressure gradient, and requires a pressure gradient for correct operation. This type of valve will allow passage of fluid from one side to the other even if it remains stationary. The helix of ‘504 is a completely different mechanical device. It is intended to propel material from one end of a cylinder to the other in a continuous fashion. Its operation does not depend on a pressure gradient. If the helix it remains stationary it will not allow passage of fluid at all. Furthermore, the ‘504 device is taught in that patent to be a continuous flow device.

Applicant’s instant invention is not a continuous flow device, but rather a pulsatile device. The helix of ‘504 will allow only continuous flow and in either of two directions. The one-way valve of the instant invention will only permit flow through it in one direction and can only accommodate a pulsatile device. To make clear this fact, claim 61 is amended to explicitly state that flow through the valve can occur in only one direction, i.e., open in one direction and closed in the opposite direction (antecedent at paragraphs 0115 and 0116), and that the system is pulsatile (antecedent at least at paragraph 0037). Applicant respectfully asks for the 102(b) rejection to be removed and the claim allowed.

Claims 32, 35-36, 39, 42-55 and 61 stand rejected under 35 USC 103(a) over Kurpanek ‘854. Examiner contends that the instant invention is merely an obvious change in the configuration or shape of the magnets taught in ‘854. Applicant respectfully disagrees. The magnets of the instant invention are rare earth bar magnets with annular magnets. The Kurpanek ‘854 pump uses a piston made of ferrous material, which is intermittently magnetically polarized following the activation of

an electromagnetic coil surrounding the the ferrous piston. The current in the coil reverses direction so as to alter the polarization of the ferrous piston. Once the piston is magnetically polarized (one direction, then the other) it shuttles back and forth between two stationary permanent rare earth bar magnets, which are in a fixed position. This ferrous piston then shuttles hydraulic fluid back and forth. The hydraulic fluid in turn surrounds two elastic membranes placed in series. The translating motion of the ferrous piston causes the elastic sacks to alternatively compress then expand, causing blood to be pumped from one sack to the next and then out of the pump. The movement of the blood through the pump is controlled by a series of electromagnetic valves.

According to the instant invention, the permanent magnet is actually the pumping member and it is made to translate by sequentially energizing the electromagnetic coils surrounding it. More importantly, the instant invention does not employ compressible sacks to pump the blood, but rather through the magnetic coupling of the blood pumping portion of the device. Neither Kurpanek '854, nor the state of the art teach, imply or motivate the skilled artisan to create the complete system of the instant invention, i.e., hydraulic drive train and blood handling pump.

The ferromagnetic piston of Kurpanek is immersed in a hydraulic fluid, such that as it translates it imparts motion to the hydraulic fluid. This fluid, in turn, causes compression of polyurethane sacks. Kurpanek additionally uses three electronically controlled valves. The instant invention uses a valve which responds to a pressure gradient, and does not comprise elastic polyurethane sacks. According to the instant invention, the hydraulic pump is a stand alone unit, remote from the blood pump. In contrast, Kurpanek's device it is a single integral unit.

Examiner, in her obviousness rejection, based her arguments on the nature of the hydraulic pump, while not addressing the blood handling portion at all. The whole invention was not considered in this rejection. Thus, Examiner has failed to establish *prima facie* case of obviousness. Applicant respectfully requests that the 103(a) rejection be removed and the claims allowed.

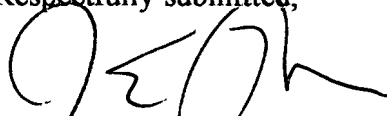
Claims 33-34, 37, 38, 40, 41 and 56-58 stand rejected under 35 USC 103(3) over Kurpanek '854. Examiner contends that Kurpanek teaches the entirety of the instant invention with the exception of the placement of the device in the patient. As described above, Kurpanek fails to teach or suggest the blood handling portion of the instant invention. Furthermore, with respect to position, the Kurpanek device is proposed as a total artificial heart, in which the heart of the patient is removed. Thus, input to the Kurpanek device is from the pulmonary vein and the output is to the aorta. To the contrary, the device of the instant invention is invented as a cardiac assist device, spliced into

the vasculature of the still-in-place heart. The instant blood-handling portion of the device is “spliced” into the long axis of the aorta or pulmonary trunk, such that, in the case of the aorta position, the pump is situated such that the input is from the aorta and output is back into the aorta. Given the vast differences in the blood handling aspects (polyurethane sacks vs. translating piston/valve assembly) and placement (how it works) of the Kurpanek device versus the instant invention, Applicant respectfully asks Examiner to withdraw the obviousness rejection and allow the claims to issue.

Claims 53, 57, 58 and 60 are objected to for informalities related to numbering and lettering of various claim elements. At the suggestion of Examiner, an additional romanette number system has been overlaid to make clearer the assignment of subelements to “major” elements.

If any other issues remain pertaining to this official action and response thereto, Examiner is invited to contact undersigned Agent.

Respectfully submitted,



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